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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,356	01/26/2004	Paul Reid	1013-3	8100

7590 03/31/2005

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,356	REID ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004 and 18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *1-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, HIV, in the reply filed on 01/18/2005 is acknowledged. Applicant's amendment to the claims to reflect Applicant's election is also noted.

Status of Claims

2. Claims 1-15 are pending.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. A sequence identifier is not attached to disclosed sequences, a CRF submission is not provided, nor is a sequence listing provided. Applicant's response to this office action must includes appropriate action(s) that would place the application in compliance with 37 CFR 1.821(a)(1) and (a)(2); otherwise the response will be treated as non-responsive.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g., line 20 of page 5 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The abstract of the disclosure is objected to because it contains an incomplete sentence, line 10 of page 41 of the specification. Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claims 1-15 are objected to because of the following informalities: As written, the claim reads on a method of dealing of, treatment of, animals that are suffering from retroviral infections; not a method of treating retroviral infections in animals that are diagnosed with retroviral infectivity. Additionally, the claims are objected to for the recitation "modified" with detoxified. With the use of "detoxified", it is abundantly clear that the venom has been modified. Ergo, the use of "modified" in the claims is considered redundant.

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim requires the method of claim 1 to further comprise a viral condition. The method of claim 1 all ready requires that the animal to have a retroviral infection. Appropriate correction is required

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5-11 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 5 and 7 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 5 recites the limitation "modified cobratoxin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 20030211465. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to the same invention, a method of treating HIV infection in an animal infected with HIV comprising the administration of a modified alpha-neurotoxin.

The difference between both claim sets is, claim 12 of '465 is directed to a genus of compounds that Applicant denotes as immunokine, whereas, claims 1-4 of the instant application is directed at alpha-neurotoxins. However, the '465 specification teaches the use of modified alpha-neurotoxin, including cobratoxin, as the preferred immunokine. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use a modified alpha-neurotoxin as the preferred immunokine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 20030211465 in view of Sanders et al. (U.S Patent No. 3888977).

Claims 5-6 limits the dose amount to.01 to 10 ml or .2 to 2ml of the composition per 150 lbs of body weight, when administered to a human, based on a .1% solution of the modified cobratoxin, which is an alpha-neurotoxin.

Claim 12 of '465 does not contain the limitations set forth in claims 5-6. However, Sanders et al. (U.S Patent No. 3888977) teaches the normal dose to administer is .05 to 10 ml and .7 to 2ml of the composition to a human per 150 lbs of body weight, based on a .1% solution of the modified cobratoxin. [Lines 24-52, column 6.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer .05 to 10 ml and .7 to 2ml of the composition to a human per 150 lbs of body weight, based on a .1% solution of the modified cobratoxin to a patient. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the dose amount is art recognized as the normal dose amount; furthermore, Applicant has not demonstrated that the claimed amount yields unexpected results.

Claims 7-9 require the composition be administered with the frequency of every other week to daily, at least weekly, and at least daily.

Claim 12 of '465 does not contain the limitations set forth in claims 7-9. However, Sanders et al. (U.S. Patent No. 3888977) suggests that administration takes place every other week, at least weekly, and every other day or daily. [Lines 24-52, column 6.] Ergo, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition every other week, at least weekly, and every other day or daily. One of ordinary skill in the art at the time the invention was made would have

been motivated to administer the composition every other week, at least weekly, and every other day or daily to a patient to optimize the treatment protocol. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the treatment schedule claimed is well known in the art; furthermore, Applicant has not demonstrated that the claimed treatment schedule yields unexpected results.

Claim 10 requires the administration be carried out by one of injection, orally, optically and by intradermal routes.

Claim 12 of '465 does not contain the limitations set forth in claim 10. However, the '465 specification teaches that administration of the immunokine can be carried out by injection, orally, optically or by intradermal routes. Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any of the listed method of administration.

Claim 11 further limits injection to subcutaneous, intramuscular, or intravenous.

Claim 12 of '465 does not contain the limitations set forth in claim 11. However, Sanders et al. (U.S Patent No. 3888977) teaches subcutaneous, intramuscular, and intravenous injections as modes of administration. It would have prima facie obvious for one of ordinary skill in the art at the time the invention was made to use one art recognized method of administration with another art recognized method of administration. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success because the method of administration is

recognized as equal substitutes for one another; Applicant has not demonstrated that the claimed treatment schedule or protocol yields unexpected results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 14-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 20030211465 in view of Sanders et al. (U.S Patent No. 3888977), as applied to claims 5 and 10, in further view of Pietras et al. (U.S. Patent No. 6306832).

Claim 14 requires the administration of benzalkonium chloride with the alpha-cobratoxin, when administered orally

Claim 12 of '465 does not teach the administration of benzalkonium chloride with the alpha-cobratoxin, when administered orally. However, Pietras et al. teaches the use of benzalkonium chloride as a preservative. Ergo, one of ordinary skill in the art at the time the invention was made would have been motivated to add a preservative to the claimed composition to extend the shelf life of the composition. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Pietras et al. teaches the use of benzalkonium chloride as a preservative.

Claim 15 requires the administration of benzalkonium chloride with the alpha-cobratoxin, wherein the cobratoxin to benzalkonium chloride ratio is between 1:6 to 1:8, and 1:7.5,when administered orally. However, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to adjust the ratios.

One of ordinary skill in the art at the time the invention as made would have been motivated to adjust the ratios to optimize the shelf life of the composition without compromising the immunogenic affect rendered by the composition. One of ordinary skill in the art would have had a reasonable expectation of success for optimizing the ratios because it is part of routine experimentation; furthermore, Applicant has not demonstrated that the claimed ration renders unexpected results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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